UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,745	04/09/2004	Michael Snyder	1030.004	1863

25215 7590 02/16/2011

DOBRUSIN & THENNISCH PC
29 W LAWRENCE ST
SUITE 210
PONTIAC, MI 48342

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
02/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/821,745
Filing Date: April 09, 2004
Appellant(s): SNYDER ET AL.

DANIEL P. ALEKSYNAS
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 17, 2010 appealing from the Office action mailed May 25, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 11 and 21-39 are pending and currently appealed.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

US 7,163,543	Smedley et al.	01-2007
US 7,354,574	Peyman	04-2008
US 4,743,255	Bardenstein	05-1988
US 6,692,759	Wong et al.	02-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(A) Claims 11, 21, 24-26, 32, 33, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smedley et al. (US 7,163,543) combined with Peyman (US 7,354,574).

Applicant Claims

Present claim 11 is directed an implantable device, comprising:

a) an implantable elongated hollow glaucoma drainage tube including a solid walled plastic lumen having a lumen section that extends into the eye and wraps generally circularly around the cornea and includes a flow passage so that when the tube is implanted within an eye the tube has a first end located in a first portion of an eye and a second end located in a second portion of the eye and the flow passage spans between the first end and the second end; and

b) a sustained release medium including caprolactone and an antimicrobial within the interior of the lumen that is filled with the sustained release medium to define a head space passage that increases its degree of opening over time as matter is passed through the lumen; wherein the lumen has a circular cross section fixed inner and outer dimension, defining a lumen diameter, the tube includes a plurality of openings of a fixed size and shape, through which the sustained release medium escapes, and the sustained release medium comprises a solid material.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Smedley teaches glaucoma treatment by permitting aqueous to flow out of the anterior chamber of the eye through a stent to Schlem's canal with one end of the stent positioned in the anterior chamber and a second end positioned in the Schlem's canal (abstract; col.3, lines 36-47). The stent contains pharmaceuticals that reduce, inhibit or slow the effects of glaucoma and heals any injury of the eye (col.3, lines 17-31). The stent is made of biocompatible material that can be metal, i.e. solid, and is coated by therapeutic agent (col.7, lines 55-63). The stent has lumen that can be circular, and has plurality of side openings (col.8, lines 1-3, 12-20; figure 3). Smedley teaches that the device can be coated or loaded within interior location, such as pores, with a slow release therapeutic active substance that have prolonged effect on the local tissue surrounding the device (col.10, lines 31-38, 60-65). The coating is expected to cover the openings as required by claims 24, 32-34. The teaching of the reference that "the therapeutic agent can be loaded in interior location of the stent", would have suggested inner surface of the lumen of the stent or within the wall. Regarding claim 38, Smedley teaches, in col.9, lines 36-46, flow restricted member that can be a polymer that reads on claim 38.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Smedley teaches loading of the device with slow release therapeutic agent and teaches interior loading, however, the reference does not explicitly teach sustained release caprolactone polymer as a release medium as instantly claimed by claim 11.

Peyman teaches implantable composition for treating ocular diseases (abstract). The composition comprises antimicrobial agent in polymer matrix of polycaprolactone contained in a diffusible walled reservoir providing sustained release composition formulated to release non-toxic therapeutic amount of the antimicrobial agent over the time (col.2, lines 9-15; col.3, lines 18-25, 42-48, 56-65).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide glaucoma treatment stent having lumen with one end positioned in the anterior chamber and a second end positioned in the Schlem's canal that can be loaded in the interior with a slow release therapeutic active substance that have prolonged effect on the local tissue surrounding the device as taught by Smedley, and provide the therapeutic agent in a polymer matrix of polycaprolactone as taught by Peyman. One would have been motivated to do so because Peyman teaches that polycaprolactone matrix provides sustained release of the contained therapeutic agent in non-toxic therapeutic amount over the time. One would reasonably expect formulating glaucoma treatment stent having lumen loaded in the interior with

polycaprolactone matrix containing therapeutic agent in order to slowly release non-toxic doses of the therapeutic agent to the surrounding and injured tissues.

Regarding the limitation of increase of the degree of opening of the head space passage as claimed by claim 11, 24, 32-33, and halting the eroded layers when the pressure is released, the combined teaching of Smedley and Peyman provides glaucoma drainage tube having in the interior a polymer composition comprising caprolactone, and it is expected that caprolactone will be eroded slowly to release the therapeutic agent, and biodegradation of the caprolactone will halt the erosion product, therefore forming the head space passage as the polymer degrades, and it is expected that by time and with erosion of the caprolactone matrix, more space is created in the stent lumen.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

(B) Claims 22, 27, 28 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Smedley and Peyman and further in view of Bardenstein (US 4,743,255).

The combined teaching of Smedley and Peyman are previously discussed as set forth in this office action.

However, the references do not teach radiologically detectable marker material as claimed by claims 22, 27, 28 and 34.

Bardenstein teaches intraocular implantable material that can be incorporated with radio-opaque marker material for follow up using simple radiological technique without resorting to complex imaging techniques (col.1, line 64-col.2, line 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent as taught by the combined teachings Smedley and Peyman, and further add radio-opaque material that can be detected by radiology to the stent as taught by Bardenstein. One would have been motivated to do so because Bardenstein teaches that radio-opaque marker material helps follow up using simple radiological technique without resorting to complex imaging techniques. One would reasonably expect formulating glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent and radio-opaque marker material that helps follow up by simple radiology technique.

(C) Claims 23, 29-31, 35-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Smedley and Peyman as applied to claims 11, 21, 24-26, 32, 33, 38 and further in view of Wong et al. (US 6,692,759).

The combined teaching of Smedley and Peyman are previously discussed as set forth in this office action.

However, the references do not teach layered sustained release material as claimed by claims 23, 29-31, 35-37 and 39.

Wong teaches ocular implantable devices for sustained release of active substances including therapeutic agents to tissues adjacent to the area of implantation (abstract; col.3, lines 32-38; col.5, lines 17-20; col.8, lines 45-64). The implant is multi-layered to deliver two or more active agents to reach different surrounding regions and particularly useful for delivering two or more active substances (col.6, lines 58-63; col.9, lines 26-30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent as taught by the combined teachings Smedley and Peyman, and further formulate the matrix as a multilayered matrix as taught by Wong. One would have been motivated to do so because Wong teaches that multi-layered implantable delivery device is particularly useful for delivering one or more active substances to the surrounding regions. One would reasonably expect formulating glaucoma treatment stent having in the interior multilayered polycaprolactone matrix containing more than one therapeutic agent and further may have radio-opaque marker to provide more than one beneficial effect to the surrounding regions to patient in need.

(10) Response to Argument

A. Appellants argue that the office action has not presented any fact findings as to where the teachings of Smedley and Peyman disclose the following elements of claims 11, 24, and 32 to 33:

First: a lumen section that extends into the eye and wraps generally circularly around the cornea.

Second: the interior of the lumen that is filled with the sustained release medium to define a head space passage.

Third: coating of the sustained release material on an exterior of the lumen and covering the openings, as claimed by claims 24, 32-34.

In response to these arguments:

First: Smedley teaches clearly, col.3, lines 36-47, glaucoma treatment by permitting aqueous to flow out of the anterior chamber of the eye through a stent to Schlem's canal **with one end of the stent positioned in the anterior chamber and a second end positioned in the Schlem's canal**. It is expressly evident in prior art teachings of figure 3 that the stent can have different shape to accommodate between the anterior chamber and Schlem's canal. It has been held by the court that aesthetic changes that have no mechanical function cannot be relied upon to patentability distinguish the claimed invention from the prior art. See *In re Seid*, 161 F.2d 229, 73 USPQ 431 (CCPA 1947). The prior art stent achieve the ultimate results as the present claims, i.e. treating glaucoma. Appellants failed to show unexpected results in treating glaucoma obtained from lumen section that extending into the eye and wrap circularly around the cornea.

Second: The stent taught by Smedley has a **lumen that can be circular, and has plurality of side openings** (col.8, lines 1-3, 12-20; figure 3). The term **"lumen" taught by the reference implied open ends as further evident by the teaching of the reference that the aqueous flows out of the anterior chamber of the eye through a stent to Schlem's canal, i.e. from one end to the other**, to define head space passage. Smedley teaches that "the therapeutic agent can be loaded in interior location of the stent", and further suggested "slow release therapeutic substance". This teaching suggests the lumen of the stent containing therapeutic agent. Peyman teaches antimicrobial agent included in polymer matrix of **biodegradable polycaprolactone** contained in an implantable composition contained in a diffusible walled reservoir providing sustained release composition formulated to release non-toxic therapeutic amount of the antimicrobial agent over the time. Therefore combination of Smedley and Peyman teaches the interior of the lumen is filled with the sustained release medium. Biodegradation of the sustained release biodegradable polymer creates head space passage.

Third: Smedley clearly teaches at col.10, lines 31-38, 60-65, that the device **can be coated** or loaded within interior location, such as pores, with a slow release therapeutic active substance that have prolonged effect on the local tissue surrounding the device. The **coating is expected to cover the openings as required by claims 24, 32-34** because the reference does not teach otherwise.

Appellants argue that the Final Rejection and Advisory Action assumes that every element of the claimed invention has been presented, and attempts to improperly shift the burden to Appellants without presenting facts that are supported by evidence found in the references of record. The addition of *Dailey* does not create a proper prima facie obviousness rejection because the court in *Dailey* presented facts as to where every element of the claimed invention may be found in the references of record, which has not been perforated for the present invention.

In response to this argument, it is argued, as addressed in this examiner answer, there is no lack of fact findings and support in the prior art or each and every element of claims 11, 24, 32-34 has been pointed out above. All the elements of the claims are taught either by the primary reference or by its combination with the secondary references, and changing the shape of the tube is a mater of design choice. **The stent of the prior art achieved the ultimate results as the present invention, i.e. drainage of the aqueous from the anterior chamber of the eye through a stent to Schlem's canal.** MPEP §2144.04 (IV)(B) similarly states that simply changing the shape of a device was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed invention was significant. The examiner believes that *In re Dailey* is applicable because it is expressly evident in prior art teachings of figure 3 that the stent can have different shape to accommodate between the anterior chamber and Schlem's canal.

Appellants argue that no facts have been provided in rejected the claim elements of “increase of the degree of opening of the head space passage as claimed by claims 11, 24, 32,33, and halting the eroded layers when the pressure is released”.

In response to this argument, it is noted from the present disclosure that the head space passage of the present invention is formed by biodegradation of the polycaprolactone, and this property will inevitably achieved from biodegradation of polycaprolactone of the prior art when inserted in the same environment since materials and their properties are inseparable. Further, the stent loaded with biodegradable material containing active agent taught by the combination of Smedley and Peyman forms one way drainage of aqueous driven by the difference between high pressure in the anterior chamber and lower pressure in and Schlem’s canal, and consequently the degraded materials will inevitably be halted in the direction of flow of the drainage because there is continuous unidirectional flow of the aqueous in the stent from the anterior chamber towards Schlem’s canal.

Appellants argue that the Final Rejection in reference to “covering the openings” states that the coating is expected to cover the openings. The word “expected” indicates that the office action could not find any factual support showing where in references of record teach “covering the openings”.

In response to this argument, it is argued that Smedley teaches coating of the stent, and does not teach any where not to coat the opening. The rationale to modify the prior art does not have to be expressly stated in the prior art; the rationale may be

expressly or impliedly contained in the prior art **or it may be reasoned from knowledge generally available to one of ordinary skill in the art and the reason to modify the reference may often suggest what the applicant has done** but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

B. Appellants argue that the office action has not presented any fact findings as to where the teachings of Smedley, Peyman, Bardenstein, and further in view of Wong disclose the following element of:

"coating of the sustained release a material on an exterior of the lumen covering the opening" so that as a layer diminishes the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release medium that is filled within the lumen escapes from the lumen, as recited by claims 34 and 35. The office action has further failed to present any fact findings as to where Smedley, Peyman, Bardenstein, and further in view of Wong teach claims 36 and 37, which state, "wherein the erosion of the layers is halted when a desired intraocular pressure is reached".

In response to the argument regarding coating and covering the opening, it is argued that Smedley clearly teaches at col.10, lines 31-38, 60-65, that the device **can be coated** or loaded within interior location, such as pores, with a slow release therapeutic active substance that have prolonged effect on the local tissue surrounding the device. The **coating is covering and would to cover the openings as required by claims 24, 32-34 since the reference does not teach the opposite.** Biodegradation of biodegradable polymer will provide the expected functions of opening the opening or widening the lumen, etc. The rationale to modify the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art **or it may be reasoned from knowledge generally available to one of ordinary skill in the art and the reason to modify the reference may often suggest what the applicant has done** but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

Regarding the argument that “as a layer diminishes the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release medium that is filled within the lumen escapes from the lumen”, it is argued that the combination Smedley and Peyman teaches stent loaded

with polymer matrix of **biodegradable polycaprolactone.** As biodegradation of polymer matrix continues, its size diminishes and inevitably increases the size of the lumen, as instantly claimed.

Regarding the argument that "erosion of the layers is halted when a desired intraocular pressure is reached", it is argued that the drainage in the stent flow in one direction driven by the difference between high pressure in the anterior chamber and lower pressure in and Schlem's canal, and consequently the degraded materials will inevitably be halted in the direction of flow of the drainage because there is continuous unidirectional flow of the aqueous in the stent, and when it pressure is equalized by flow of the aqueous will stop as well as halting of the degraded material, if any left.

It has been held that if the prior art meets the structure recited, the properties must be met or Applicant's claim is incomplete. This is in line with *In re Spada*, 15 USPQ 2d 1655 (1990).

Appellants argue that the statement of the rejection of claims 23, 29-32, 35-37 and 39 over the combination of Smedley with Peyman and Wong lacks clarity. The examiner reviewed the statement, there was a typographical error inadvertently made in view of new claims added and renumbering of the claims. However it is clear in view of the non-final office action as currently rewritten.

The examiner believes that the facts presented by the office action are clearly supported by evidence from the cited references.

C. Appellants argue that the absence of fact finding precludes a proper analysis under KSR from which to conclude that the combination is obvious.

Appellants argue that in view of the absence of fact findings a proper analysis under KSR was not performed. By way of example, no analysis shows how any of the structures in the prior art have a head space that increases over time, as is found in claim 11. Appellants hereby repeats the limitation they believe lack fact finding in the prior art and further argue that if no fact findings have been performed regarding an element then no apparent reason can be provided for combining that element under KSR, and a proper prima facie obviousness rejection cannot be made.

In response to the argument regarding fact finding, it is repeated that each element of the claims, **either structural or functional**, has been pointed out in this examiner's answer. Each element has been contained in the prior art **either expressly or impliedly** as set forth in this examiner answers. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to

achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Further it is argued that **motivation to combine the cited prior art** as well as **reasonable expectation to arrive to the present invention do exist,** and clear statements of motivation were stated in the rejection, as set forth in this examiner's answer. Additionally, the references are combinable because the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all the references are in the field of applicant's endeavor.

Additionally, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex,*

Inc., 550 U.S. 398, 82 USPQ2d 1385 (2007). See the rejections as set forth in this examiner's answer. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Finally, it is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

D. Appellants argue that the proposed modification cannot render the prior art unsatisfactory for its intended purpose, violating MPEP 2143,01V.

The modification proposed in the office action that allegedly renders claims 38 and 39 obvious is believed to render Smedley unsatisfactory for its intended purpose. Appellants do not believe that the facts as alleged are supported by the evidence found in Smedley. Claim 38 states, "wherein the device includes a focal surrounding element that can be altered to shrink and constrict the lumen". The office action cites col. 9, lines 36-46 that teaches "flow restricted member may be situated in any location in the device

such that blood flow is restricted form retrograde motion. This modification render the prior art unsatisfactory for its intended use. The Final Rejection did not present any additional facts or evidence explaining how these references cure the defects described herein for claim 39.

In response to this argument, it is argued that the flow restricted element taught by the Smedley is taught to be capable to be i**nserted anywhere in the device**. So it can be also used to restrict the flow of any fluid including aqueous. In absence of claiming any structure of flow restricted member, then the one taught by the prior art reads on the claimed member. Claim 39 rejected over Smedley, Peyman and Wong, and the same argument applied for claim 38 will apply for claim 39.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Isis A Ghali/
Primary Examiner, Art Unit 1611

Conferees:

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612